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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,665	11/17/2003	Mark Selby	PP01635.007	5235
27476 7590 12/12/2007 NOVARTIS VACCINES AND DIAGNOSTICS INC. INTELLECTUAL PROPERTY R338 P.O. BOX 8097 Emeryville, CA 94662-8097			EXAMINER LUCAS, ZACHARIAH	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/715,665	Applicant(s) SELBY ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 34,42,45,66,69,77,80-86 and 88-92 is/are pending in the application.  
     4a) Of the above claim(s) 80-84 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45,69,88 and 92 is/are allowed.
- 6) ☒ Claim(s) 34,42,66,77,85,86 and 89-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Currently, claims 34, 42, 45, 66, 69, 77, 80-86, and 88-92 are pending in the application.
2. In the prior action, claims 34, 42, 45, 66, 69, 77, 80-85, and 88-91 were pending; with claims 80-84 withdrawn as to non-elected inventions; claims 45, 69, and 88 objected to, and claims 34, 42, 66, 77, 85, 86, and 89-91 rejected.
3. In the amendment of October 9, 2007, the Applicant amended claims 45, 69, and 88; and added new claim 92.
4. Currently, claims 34, 42, 45, 66, 69, 77, 85, 86, and 88-92 are pending and under consideration.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **(Prior Rejection- Maintained)** Claims 34, 42, and 66 were rejected under 35 U.S.C. 103(a) as being unpatentable over Major et al. (J Virol 69: 5798-5805) in view of Michalak et al., (J Gen Virol 78: 2299-2306) and Valenzuela et al. (Bio/Technology 3: 323-26) as applied previously, and further in view of Ono et al. (Nuc Acids Res 11: 1747-1757), Choo et al. (PNAS 88:2451-55), and Chapman et al. (Nuc Acids Res 19:3979-86). Several arguments in traversal are presented.

The Applicant first notes deficiencies in the teachings of the individual references. In response to these arguments against the references individually, it is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). These arguments are therefore not found persuasive.

The Applicant traverses the rejection on the grounds that 1) there must be a suggestion or motivation to modify or combine the prior art, and 2) that the rejection of claims cannot be predicated on the mere identification in a reference of individual components of the claimed invention. These arguments are noted but are not found persuasive. In the statements of the rejection (see e.g., Action of July 29, 2005, pages 6-8; and the Action of May 4, 2007, pages 3-5), it was pointed out both how the references teach each of the limitations of the claimed inventions, and why it would have been obvious to those of ordinary skill in the art to combine them. As the statement of the rejection sets forth why it would have been obvious to those of ordinary skill in the art to combine the teachings of the cited references, and as the Applicant has not provided any argument as to why such would not be the case, the arguments are not found persuasive.

7. The Applicant also asserts on page 9 that the Office has not provided evidence that those of ordinary skill in the art would have expected the resulting fusion protein to be an effective anti-HCV immunogen, or that such would be expected to form HBV particles. First, it is noted that none of the presently rejected claims require the formation of HBV particles. Although the claims are interpreted in light of the specification, limitations from the specification are not read

into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, this argument is not found persuasive. With respect to the assertion that there would have been no expectation that the fusion proteins would be effective anti-HCV immunogens, Applicant's attention is directed to the statement of the rejection on pages 7 and 8 of the July 2005 action. As the Applicant has provided no evidence contradicting the teachings referred to therein, this portion of the argument is also not found persuasive.

For the reasons above, and the reasons of record, the rejection is maintained.

8. **(Prior Rejection- Maintained)** Claim 77 was rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (U.S. 6,306,625), in view of Major, Michalak, and Valenzuela and further in view of Ono, Choo, and Chapman as applied against claims 34, 42, and 66 above. The Applicant traverses this argument for the same reasons as indicated with respect to the rejection of claims 34, 42, and 66 above. It is noted that claim 77 does require the formation of HBV particles. However, the additional teachings of Jacobs do provide those of ordinary skill in the art with a reasonable expectation of success in the formation of such particles. See e.g., action of July 2005, page 9. The arguments are therefore not found persuasive for the reasons above, and the reasons of record. The rejection is therefore maintained.

9. **(Prior Rejection- Maintained)** Claims 85 and 86 were rejected under 35 U.S.C. 103(a) as being unpatentable over Major, Michalak, and Valenzuela in view of Ono, Choo, and Chapman as applied above, and further in view of Jacobs (*supra*), De Wilde et al. (U.S. 5,928,902), U.S. 4,722,840 (the 840 patent), and Mountford et al (PNAS 91: 4303-07). The

Applicant traverses this argument for the same reasons as indicated with respect to the rejection of claims 34, 42, and 66 above. The arguments are not found persuasive for the reasons above, and the reasons of record. The rejection is therefore maintained.

10. **(Prior Rejection- Maintained)** Claims 89-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Major, Michalak, and Valenzuela, in view of Ono, Choo, and Chapman as applied against claims 34, 42, and 66 above, and further in view of the teachings of Maertens et al. (6,890,737) or of Flint et al. J Virol 73: 6782-90). The Applicant traverses the rejection on substantially the same grounds as argued above. The Applicant again provides no evidence in support of their assertions of non-obviousness, although grounds as to why it would have been obvious to those of ordinary skill in the art to combine the teachings of the cited references, and as why there would have been a reasonable expectation of success in doing so have been provided. The rejection is therefore maintained for the reasons above and the reasons of record.

### ***Conclusion***

11. Claims 45, 69, and 88 appear to be allowable over the prior art. The prior art does not appear to teach or suggest the vector of SEQ ID NO: 6.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. Lucas/  
Patent Examiner, AU 1648